UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590 03/04/2009

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/060,849	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/08 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33, 35, 38-40, 71-97, 112-132 and 134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that the present specification does not provide support for the limitation "wherein the extruded capsule shell composition is substantially pH-independent". Contrary to the limitation in the claims, the examples from the present specification show that the

release of active agent from the capsule is indeed a pH-dependent. See for example, pages 45 and 48 for the dissolution rate at pH greater than 6 or 7.5.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "*at least one* dissolution modifying excipient" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite this limitation. Claim 1 requires *at least two* dissolution modifying excipients in the use of the phrase "combination".

Claim Rejections - 35 USC § 103

Claims 1, 2, 7-16, 20-22, 39, 40, 73, 74, 81-74, 87-90, 92-95, 112 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189.

Petereit teaches an injection molding composition comprising: a) 45-100% methacrylate copolymer; b) 0.1-3% lubricant; c) 0-50% drier; d) 0-30% plasticizer; e) 0-100% additives or auxiliaries; f) active agent; and g) 0-20% of another polymer or copolymer (paragraphs 0019-0027). Methacrylate copolymer includes 50-70% methyl acrylate, 10-30% methyl methacrylate, and 5-15% methacrylic acid (a 7:3:1 ratio if converted) (paragraph 0038). Plasticizer includes castor oil, sorbitan ester, and

polyethylene glycol (paragraphs 0050-0051). Other polymer or copolymer includes polyvinyl pyrrolidone (paragraphs 0078-0080). Petereit further teaches the shape of the molding includes capsule, part of a capsule such as half or a capsule (paragraph 0095). Petereit also teaches the wall thickness of the obtained capsule is of 0.6 mm (paragraph 0101).

Petereit does not explicitly teach the claimed percent amount of lubricant from 5% to about 30%. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select a lubricant amount that falls within the claimed range with the expectation of lat least similar result. This is because Petereit teaches the use of the same lubricant, such as stearyl alcohol, for the same purpose, namely, as a mold releasing agent (paragraphs 0041-0044). Further, the use of lubricant as a mold releasing agent in the claimed amount is known in the art. See for example the teaching of Lehmann at column 3, lines 65-67; and example 1. Lehmann teaches the use of 6% of the mold releasing agent, based on the weight of the polymer. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the molding composition of Petereit using lubricant in the claimed amount in view of the teachings of Lehmann.

Petereit further does not teach that the capsule shell composition is substantially pH-independent. It is noted that nowhere in Petereit does the teaching of pH-dependent disclose. Accordingly, the burden is shifted to applicant to show that the capsule composition of Petereit is substantially pH-dependent. This is because Petereit teaches the use of the same polymers and in the same amounts to prepare a composition for the same purpose desired by the applicant, namely, a capsule shell composition useful in pharmaceutical art.

Claims 3-6, 18 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Bolles US 3,779,942 and Zentner US 4,795,644.

Petereit is relied upon for the reason stated above. Petereit does not expressly teach the use of surfactant.

Bolles teaches a capsule shell composition comprising well known polymer such hydroxypropyl cellulose, and surfactant such as sodium dioctyl sulfosuccinate in an amount of from about 0.001-10% (abstract; and column 2, lines 20-59). Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include surfactant to obtain the claimed invention. This is because Bolles teaches that the addition of surfactant to improve capsule shell storage stability, uniformity and strength (abstract; and column 2, lines 2-8).

Bolles does not teach the claimed surfactant such as sodium dodecyl sulfate. Zentner teaches useful surfactant for wall forming composition includes sodium dodecyl

sulfate, and sodium dioctyl sulfosuccinate (column 13, lines 53 through column 14, lines 1-22). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select sodium dodecyl sulfate as a surfactant, because Zentner teaches the equivalency between sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate, and because Zentner teaches the use of sodium dodecyl sulfate in wall forming composition is known in the art.

Claims 1-33, 35, 38-40, 71-97, 112-132 and 134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189, Hatano et al. US 6,309,666, and Klug et al. US 3,314,809.

Petereit is relied upon for the reasons stated above. Petereit further does not teach the inclusion of additives such as lactose and mannitol.

Hatano teaches coated capsule compositions comprising a hard outer shell (abstract). The compositions may be formulated for quick release at a desired location in the gastrointestinal tract (column 2, lines 49-62). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (column 5, line 42 to column 6, line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include mannitol, lactose and starch. Binders include ethylcellulose, polyvinylpyrrolidone, HPMC, and polyethylene glycol (column 12, lines 1-11). Disintegrants include polyvinylpyrrolidone and hydroxypropylcellulose (column 12, lines 12-17). Lubricants

and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene sorbitan monooleate, poiyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (column 11, line 52 to column 12, line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (column 13, lines 3-5). Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include the excipients in view of the teachings of Hatano. This is because Hatano teaches the use of well known excipients in pharmaceutical art in capsule shell composition, and because Petereit teaches the desirability of using excipients or other auxiliaries known in the art.

It is noted that applicant argues that Petereit teaches the use of HPC in a long list, and there is no motivation to select HPC. However, Klug teaches a capsule shell composition comprising HPC (columns 1-2). Thus, the skilled artisan would have been motivated to select HPC as other polymer for the capsule shell composition of Petereit in view of the teachings of Klug, because Klug teaches that HPC is the stable thermoplastic material for making excellent articles such as capsule shell (column 4, lines 56 through column 5, lines 1-15).

Response to Arguments

Applicant's arguments filed 12/23/08 have been fully considered but they are not persuasive.

Applicant argues that nothing in either the Petereit or the Hatano reference teaches, suggests, motivates, or provides any reason, or in fact even remotely enables, the substantially pH-independent composition of the present invention which make of the capsule shell and linker as claimed herein.

However, in response to applicant's arguments, it is noted that nowhere in the Petereit reference does the teaching of pH-dependent disclose. In other word, nothing in Petereit teaches that the capsule shell composition is a pH dependent as alleged by applicant. Moreover, Petereit teaches the use of the same copolymer and in the same amount. Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Applicant pointed to example 1 of Petereit for the teaching that the molding is soluble in intestinal fluid. However, such teaching does not in any way indicate that the capsule shell does not release active agent in the stomach or through the GI tract, or the shell is pH-dependent. Further, Petereit cannot be relied upon solely for the teaching in the example. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983).

Applicant argues that Hatano teachings are clearly directed to pH dependent composition. In response to applicant's argument, the test for obviousness is not

whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Hatano is relied upon solely for the teachings of well known pharmaceutically acceptable excipients useful in capsule art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615